



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2011-0966; FRL-9359-3]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR, entitled: “Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)” and identified by EPA ICR No. 2249.03 and OMB Control No. 2070-0176. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the information collection.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0966, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2011-0966. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2011-0966. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: William Wooge, Office of Science Coordination and Policy (OSCP) (7203M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8476; fax number: (202) 564-8482; e-mail address: wooge.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to section 3506(c)(2)(A) of PRA (44 U.S.C. 3501 *et seq.*), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Should I Consider when I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the collection activity.
7. Make sure to submit your comments by the deadline identified under **DATES**.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

III. What Information Collection Activity or ICR Does this Action Apply to?

Affected entities: Entities potentially affected by this ICR are those individuals and companies that receive an EDSP test order issued by the Agency. Under section 408(p)(5)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)(5)(A)), EPA “shall issue” EDSP test orders “to a registrant of a substance for which testing is required . . . or to a person who manufactures or imports a substance for which testing is required.” Using the North American Industrial Classification System (NAICS) codes, the Agency has determined that potential respondents to the information collection covered in this ICR may include, but is not limited to: Chemical manufacturers and processors (NAICS code 325); pesticide, fertilizer, and other agricultural chemical manufacturing (NAICS code 3253); producers & formulators of pesticide products (NAICS code 32532); producers of antifouling paints (NAICS code 32551); producers of antimicrobial pesticides (NAICS code 32561); producers of nitrogen stabilizers (NAICS code 32531); and producers of wood preservatives (NAICS code 32519).

Title: Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP).

ICR number: EPA ICR No. 2249.03.

OMB control number: OMB Control No. 2070-0176.

ICR status: The existing ICR approval is currently scheduled to expire on October 31, 2012. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information covered by the PRA, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This is a renewal of an existing ICR covering the information collection activities associated with Tier 1 screening of chemicals under EPA's EDSP. The EDSP is established under FFDCA section 408(p), which requires EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. The EDSP consists of a two-tiered approach to screen chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. Substances that have the potential to interact with estrogen, androgen or thyroid systems may proceed to Tier 2, which is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect. Additional information about the EDSP is available through the Agency's web site at <http://www.epa.gov/endo>.

This ICR addresses the information collection activities for the first list of chemicals screened under Tier 1 of the EDSP, and covers the full range of information collection activities associated with the issuance of and response to Tier 1 EDSP orders issued by EPA. The first list was established in 2009, and consists of 67 pesticide active ingredients (PAIs) and pesticide inerts. As the renewal of an ongoing information collection activity approved under the PRA, this ICR addresses the paperwork burden associated with the continuation of these activities over the next three years. As such, the paperwork burdens are adjusted to reflect the planned progression associated with the information collection activities covered by the ICR.

As such, the renewal ICR does not include the proposed addendum that was issued for public comment in the **Federal Register** of November 17, 2010 (75 FR 70568) (FRL 8849-3).

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 204 and 4,833 hours, depending on the respondent category, with an estimated cost between \$17,076 and \$278,966. Burden is defined in 5 CFR 1320.3(b). The ICR provides a detailed explanation of this estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 264.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 106,416 hours.

Estimated total annual costs: \$6,152,254.

IV. Are There Changes in the Estimates from the Last Approval?

There is a decrease of 54,999 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's adjustment in burden estimates due to the planned progression of the collection activities associated with the first list of chemicals to be screened under the EDSP. This change is an adjustment.

V. What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: July 31, 2012.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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